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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,907	04/21/2000	Holly Horton	1530.0060004/EKS/EJH	9397

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005

EXAMINER
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WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

26

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/557,907

Applicant(s)

HORTON ET AL.

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,16-18,30-35,38-41,43,46-50,66,69,71-74,77,78 and 83-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,16-18,30-35,38-41,43,46-50,66,69,71-74,77,78 and 83-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☒ Interview Summary (PTO-413) Paper No(s). 25.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                      6) ☐ Other:

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on 5-5-03 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/557907 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78 and 83-86 remain under consideration in the instant office action. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants have not amended the claims or provided any new arguments.

### ***Specification***

The abstract of the disclosure is objected to because it is not descriptive of the claimed invention. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Objections***

In claim 1, 66 and 78, "through operable association with" should be changed to -operably associated with--.

In claim 3, "in operable association with" should be changed to --operably associated with--.

In claims 16 and 17, " " should be changed to --alpha--.

In claim 18, --plasmid-- should be inserted after "said DNA".

***Claim Rejections - 35 USC § 112***

Claims 16 and 18 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because they are dependent upon a canceled claim. It appears that claims 16 and 18 should be dependent upon claim 1.

***Double Patenting***

Claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78 and 83-86 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 164, 185, 189, 201, 202, 206, 207, 209, 210, 212, and 213 of copending Application No. 09/839574 in view of Dalglish (1995, Cancer Surveys, Vol. 296, pg 289-320). The claims of '574 teach administering plasmid DNA encoding IFN- $\alpha$  into skeletal muscle or intraperitoneally to treat disease. The claims of '574 do not specifically require treating cancer. Treating disease in claims 201, 202 et al. of '574 is a genus to treating cancer as claimed in the instant invention. Using DNA at a concentration of 1-30 ng and salt at 20-300 mM as in '574 is an obvious species of the instant invention. However, Dalglish taught treating cancer using IFN-alpha. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administering plasmid DNA encoding IFN-alpha into skeletal muscle or intraperitoneally to treat disease as taught in '574 to treat cancer as taught by Dalglish. One of ordinary skill in the art at the time the invention was made would have been motivated to use the method of '574 to treat cancer using IFN-alpha to

reduce tumors. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-6, 16-18, 30-35, 38-41, 43 and 46-50 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48, 52, 57, 59, 61, 72, 74, 76, 77, 79, 81, 82 and 84 of copending Application No. 09/588655 in view of Dalglish (1995, Cancer Surveys, Vol. 296, pg 289-320). The claims of '655 teach administering plasmid DNA encoding IFN into heart muscle and obtaining activity of the protein. The claims of '655 do not specifically require treating cancer or that the IFN is IFN-alpha. Obtaining physiologically active expression of a protein as in claims 81, 82 and 84 of '655 is a genus to treating cancer as claimed in the instant invention. Administering DNA to the heart as in '574 is an obvious species of "muscle" as claimed in the instant invention. However, Dalglish taught treating cancer using IFN-alpha. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administering plasmid DNA encoding IFN into the heart and obtain activity of IFN claimed in '574 to treat cancer using IFN-alpha as taught by Dalglish. One of ordinary skill in the art at the time the invention was made would have been motivated to use the method of '574 to treat cancer using IFN-alpha to reduce tumors. This is a provisional obviousness-type double patenting rejection because, while the claims have been allowed, the claims have not yet been patented.

Claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78 and 83-86 remain provisionally rejected under the judicially created doctrine of obviousness-type

double patenting as being unpatentable over the claims of copending Application No. 10/028782. Although the conflicting claims are not identical, they are not patentably distinct from each other because they have the same limitations and are co-extensive. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

This is a CPA of applicant's earlier Application No. 09/557907. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

No claim is allowed.

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Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

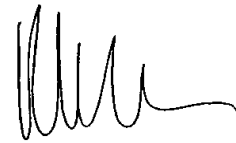
Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



**MICHAEL WILSON**  
**PRIMARY EXAMINER**